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Substitute for form 1449/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet

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of

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### Complete if Known

Application Number	10/750,475
Filing Date	12-31-2003
First Named Inventor	Alavattam et al.
Art Unit	1653
Examiner Name	Gergi, Ray <i>Max</i>
Attorney Docket Number	13447

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
<i>Max</i>	A1	US- 3,773,919	11-20-1973	Boswell et al.	
<i>Max</i>	A2	US- 3,887,699	06-03-1975	Yolles	
<i>Max</i>	A3	US- 4,293,339	10-06-1981	Supcoe et al.	
<i>Max</i>	A4	US- 4,675,189	06-23-1987	Kent et al.	
<i>Max</i>	A5	US- 5,700,486	12-23-1997	Canal et al.	
<i>Max</i>	A6	US- 5,759,583	06-02-1998	Iwamoto et al.	
<i>Max</i>	A7	US- 5,981,719	11-09-1999	Woiszwiller et al.	
<i>Max</i>	A8	US- 5,985,309	11-16-1999	Edwards et al.	
<i>Max</i>	A9	US- 6,120,787	09-19-2000	Gustafsson et al.	
<i>Max</i>	A10	US- 6,238,705	05-29-2001	Liu et al.	
<i>Max</i>	A11	US- 6,294,202	09-25-2001	Burns et al.	
<i>Max</i>	A12	US- 6,391,296	05-21-2002	Okano et al.	
<i>Max</i>	A13	US- 6,896,894	05-24-2005	Brody et al.	
		US-			

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> "Number" <sup>4</sup> "Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
<i>Max</i>	A14	EP 0 950 663 A1	10-20-1999	Okano et al.		
<i>Max</i>	A15	WO 02/28370 A1	04-11-2002	Jonsson et al.		

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete If Known</b>	
				Application Number	10/750,475
				Filing Date	12-31-2003
				First Named Inventor	Alavattam et al.
				Art Unit	1653
				Examiner Name	Sergi, Rey <i>UR</i>
Sheet	2	of	6	Attorney Docket Number	13447

<b>NON PATENT LITERATURE DOCUMENTS</b>						
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				T <sup>2</sup>
<i>MR</i>	B1	AUSTIN et al.; The Controlled Release of Leukaemia Inhibitory Factor (LIF) From Alginic Gels; Pro Intern Symp Control Rel Bioact Mater; 23; 1996; pp 739-740				
<i>MR</i>	B2	BRANNON-PEPPEAS et al.; Polyactic and Polyglycolic Acids as Drug Delivery Carriers; Handbook of Pharmaceutical Release Tech; 2000; pp 99-130; Marcel Dekker; New York				
<i>MR</i>	B3	BURGESS et al.; Glucuronidase Activity Following Complex Coacervation & Spray Drying Microencapsulation; J. Microencapsulation; 1998; Vol 15; No. 5; pp. 569-579				
<i>MR</i>	B4	BURKE, PAUL; Controlled Release Protein Therapeutics: Effects of Process & Formulation on Stability; Handbook of Pharmaceutical Controlled Release Tech; 2000; pp. 661-692;				
<i>MR</i>	B5	CHANG, THOMAS; Biodegradable Semipermeable Microcapsules Containing Enzymes Hormones Vaccines & Other Biologicals; J of Bioengineering; 1976; Vol 1; pp 25-32				
<i>MR</i>	B6	CHEN et al. Polysaccharide Hydrogels for Protein Drug Delivery; Carbohydrate Polymers 28; 1995; pp 69-76; Elsevier; Great Britain				
<i>MR</i>	B7	CLELAND et al.; Stable Formulations of Recombinant Human Growth Hormone & Interferon-for Microencapsulation in Biodegradable Microspheres; Pharmaceutical Research; Vol 13; No 10; 1996; pp. 1464-1475				
<i>MR</i>	B8	CROTTES et al. Protein Delivery From Poly(lactic-co-glycolic acid) Biodegradable Microspheres: Release Kinetics & Stability Issues; J Microencapsulation 1998; 15; 6; pp 699-713				
<i>MR</i>	B9	DE ROSA et al; Influence of Co-encapsulation of Different Non-Ionic Surfactants on the Properties of PLGA Insulin-loaded Microspheres; J Controlled Release 69 2000 pp 283-295				

Examiner Signature	<i>Rey UR</i>	Date Considered	2/15/06
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STATEMENT BY APPLICANT

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Application Number

10/750,475

Filing Date

12-31-2003

First Named Inventor

Alavattam et al.

Art Unit

1653

Examiner Name

Gargi, Roy *UW*

Attorney Docket Number

13447

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<i>MR</i>	C1	GOMBOTZ et al.; Protein Release From Alginate Matrices; Advanced Drug Delivery Reviews; 31; 1998; pp 267-285; Elsevier	
<i>MR</i>	C2	HUANG et al.; On The Importance & Mechanisms of Burst Release in Matrix-controlled Drug delivery Systems; J of Controlled Release; 73; 2001; pp 121-136; Elsevier	
<i>MR</i>	C3	JAIN et al.; Controlled Drug Delivery by Biodegradable Poly(Ester) Devices: Different Preparative Approaches; Drug Development & Industrial Pharmacy; 1998; Vol 24; pp 703-727	
<i>MR</i>	C4	JIANG et al.; Stabilization & Controlled Release of Bovine Serum Albumin Encapsulated in Poly(D, L-lactide) and Poly(ethylene glycol) Microsphere Blends; Pharmaceutical Research; Vol 18; 6; 2001; pp 878-885	
<i>MR</i>	C5	JOHANSEN et al.; Improving Stability & Release Kinetics of Microencapsulated Tetanus Toxoid by Co-Encapsulation of Additives; Pharmaceutical Research Vol 15; 7 1998 pp 1103-1110	
<i>MR</i>	C6	LEE et al.; Double Walled Microparticles For HBV Single Shot Vaccine; Proceed Intern Symp Control Rel Bioact Mater; 23; 1996; pp 333-334; #4103; Controlled Release Soc	
<i>MR</i>	C7	LI et al.; A Novel Biodegradable System Based on Gelatin Nanoparticles and Poly(lactic-co-glycolic acid) Microspheres for Protein and Peptide Drug Delivery; J Pharmaceutical Sciences; Vol 86; No 8; August, 1997; pp 891-895	

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Sheet

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Application Number

10/750,475

Filing Date

12-31-2003

First Named Inventor

Alavattam et al.

Art Unit

1653

Examiner Name

Gargi, Ray, Wax

Attorney Docket Number

13447

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<i>MM</i>	D1	MORLOCK et al.; Erythropoietin-Loaded Microspheres Prepared From Biodegradable-LPLG-POE-LPLG Triblock Copolymers: Protein Stabilization and In-vitro Release Properties;	
		J of Controlled Release; 56; 1998; pp 105-115; Elseview	
<i>MM</i>	D2	PARK et al.; Poly(L-lactic acid) Pluronic Blends: Characterization of Phase Separation Behavior, Degradation and Morphology and Use as Protein-Releasing Matrices;	
		Macromolecules; 1992; 25; pp 116-122; American Chemical Society	
<i>MM</i>	D3	PATIL et al.; Water-Based Microsphere Delivery System for Proteins; J of Pharmaceutical Sciences; Vol 89; No 1; January 2000; pp 9-15	
<i>MM</i>	D4	PEAN et al.; Why Does PEG 400 Co-Encapsulation Improve NGF Stability & Release From PLGA Biodegradable Microspheres; Pharmaceutical Research; Vol 16; No 8; 1999; pp 1294-1299	
<i>MM</i>	D5	PROKOP et al.; Water Soluble Polymers for Immunoisolation II: Evaluation of Multicomponent Microencapsulation Systems; Advances in Polymer Science; Vol 136; pp 53-73; 1998	
<i>MM</i>	D6	PUTNEY et al.; Encapsulation of Proteins for Improved Delivery; Current Opinion In Chemical Biology; 1998; 2 pp 548-552	
<i>MM</i>	D7	ROSKOS et al.; Degradable Controlled Release Systems Useful for Protein Delivery; Protein Delivery: Physical Systems, Sanders & Hendren eds.; Plenum Press; NY; pp 45-92; 1997	

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				First Named Inventor	Alavattam et al.
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Sheet 5	of	6	Attorney Docket Number	13447	

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<i>MR</i>	E1	SANCHEZ et al.; Formulation Strategies for Stabilization of Tetanus Toxoid in Poly(lactide-co-glycolide) Microspheres; Inter J of Pharmaceutics; 185; 1999 pp 255-266; Elsevier				
<i>MR</i>	E2	SANDOR et al.; Effect of Protein Molecular Weight on Release From Micro-Sized PLGA Micoospheres; J of Controlled Release; 76; 2001; pp 297-311; Elsevier				
<i>MR</i>	E3	SEZER et al.; Release Characteristics of Chitosan Treated Alginate Beads: I. Sustained Release of a Macromolecular Drug From Chitosan Treated Alginate Beads; J Microencapsulation; 1999; Vol 16; No 2; pp 195-203				
<i>MR</i>	E4	Van DE WEERT et al.; Protein Instability in Poly(Lactic-co-Glycolic Acid) Microparticles; Pharnaceutical Research; Vol 17; No 10; 2000; pp 1159-1167				
<i>MR</i>	E5	WAKEMAN et al.; Concentration and Fractionation of Polyvinyl Alcohol-anionic Surfactant Stabilised Latex Dispersions by Microfiltration; J-Membrane Science; 106; 1995 pp 57-65				
<i>MR</i>	E6	WANG et al.; A heterogenously Structured Composite Based on Poly(lactic-co-glycolic acid) Microspheres and Poly (vinyl alcohol) Hydrogel Nanoparticles for Long-Term Protein Drug Delivery; Pharmaceutical Research; Vol 16; No 9; 1999; pp 1430-1435				
<i>MR</i>	E7	WANG et al.; A Novel Approach to Stabilization of Protein Drugs in Poly(lactic-co-glycolic acid)microspheres Using Agarose Hydrogel; International Journal of Pharmaceutics; 166; 1998; pp 1-14				

Examiner Signature	<i>Lathe</i>	Date Considered
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Examiner Name	Gargi Roy Wax		
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<i>MR</i>	F2	WOO et al.; Preparation and Characterization of a Composite PLGA and Poly(Acryloyl Hydroxyethyl Starch) Microsphere System for Protein Delivery; Pharmaceutical Research; Vol 18; No. 11; November, 1002; pp 1600-1606	
<i>MR</i>	F3	ZHU et al.; Stabilization of Proteins Encapsulated in Injectable Poly(lactide-co-glycolide); Nature Biotechnology; Vol 18; January, 2000; pp 52-57	

Examiner Signature	<i>Erin Roy</i>	Date Considered	2/15/06
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